RD2008-08

Registration Decision

Foramsulfuron Technical Herbicide

(publié aussi en français)

25 July 2008

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9

Internet: pmra_publications@hc-sc.gc.ca
www.pmra-arla.gc.ca
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra_infoserv@hc-sc.gc.ca

Canada

ISBN: 978-1-100-10317-4 (978-1-100-10318-1)
Catalogue number: H113-25/2008-8E (H113-25/2008-8E-PDF)

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Table of Contents

Registration Decision for Foramsulfuron Technical Herbicide 1
What Does Health Canada Consider When Making a Registration Decision? 1
What Is Foramsulfuron Technical Herbicide? 2
Health Considerations 2
Environmental Considerations 4
Value Considerations 5
Measures to Minimize Risk 5
Other Information 6
Appendix I Comments and Responses 7
References 9

Registration Decision for Foramsulfuron Technical Herbicide

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Foramsulfuron Technical Herbicide and Option 35 DF Herbicide containing the technical grade active ingredient foramsulfuron to control certain broadleaf and grassy weeds in field corn in Eastern Canada and Manitoba. However, the toxicity of Option 2.25 OD Liquid Herbicide to aquatic vascular plants is still unknown. Therefore, full registration cannot be granted for this end-use product at this time.

Current scientific information was evaluated to determine if, under the proposed conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document:[1] Proposed Registration Decision PRD2008-05, *Foramsulfuron Technical Herbicide*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for Foramsulfuron Technical Herbicide and summarizes the Agency's decision, the reasons for it and provides, in Appendix I, a summary of comments received during the consultation process as well as the PMRA's response to these comments. This decision is consistent with the proposed registration decision stated in PRD2008-05.

For more details on the information presented in this Registration Decision, please refer to PRD2008-05, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration.[3] The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act.*

[2] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act.*

[3] "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act.*

[4] "Value" as defined by subsection 2(1) of the *Pest Control Products Act:* "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies hazard and risk assessment methods as well as policies that are rigorous and modern. These methods consider the unique characteristics of sensitive subpopulations in both humans (e.g. children) and organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at www.pmra-arla.gc.ca.

What Is Foramsulfuron Technical Herbicide?

Foramsulfuron is the active ingredient in the herbicide end-use products Option 35 DF Herbicide and Option 2.25 OD Liquid Herbicide. These end-use products are applied after the weeds emerge (postemergence) and will provide control of specific broadleaf weeds and grasses in field corn.

Health Considerations

Can Approved Uses of Foramsulfuron Technical Herbicide Affect Human Health?

Foramsulfuron is unlikely to affect your health when used according to the proposed label directions.

Potential exposure to foramsulfuron may occur through diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur, and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which exposure is expected to be well below levels that cause no anticipated effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100 times higher (and often much higher) than levels to which humans are normally exposed when using foramsulfuron products according to label directions.

Foramsulfuron does not require any further label statements as there were no significant effects on animals during acute testing. End-use product Option 2.25 OD Liquid Herbicide caused moderate dermal irritation and was a skin sensitizer. Consequently, the label statement "Warning—Skin Irritant and Potential Skin Sensitizer" is required. The other formulation, Option 35 DF Herbicide, caused moderate dermal irritation, mild eye irritation and was a skin sensitizer. As a result, the following label statement is required: "Warning—Skin and Eye Irritant and Potential Skin Sensitizer."

Foramsulfuron did not cause cancer in animals and the weight of evidence indicates it is not genotoxic. There was also no indication that foramsulfuron caused damage to the nervous system and there were no effects on reproduction. Foramsulfuron is of low toxicity over long periods and did not demonstrate any effects on any organs at the highest dose tested. The risk assessment used the highest dose tested in the chronic studies, where no effects were observed. No endpoints of concern were noted. However, the risk assessment protects against potential effects by ensuring that the level of human exposure is well below the dose at which no effects were found.

When foramsulfuron was given to pregnant animals, no effects were observed on the mothers, the developing fetus or the young animals. This indicates that the fetus and young animals were not more sensitive than the mothers and specific protection is not required in the risk assessment.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Aggregate dietary risk estimates (food and water) revealed that the general population and infants, the population group that would ingest the most foramsulfuron relative to body weight, are expected to be exposed to negligible risk levels (i.e. much less than 1% of the acceptable daily intake). Based on these estimates, the chronic dietary risk from foramsulfuron is not of concern for all population subgroups.

Animal studies revealed no acute health effects. Consequently, a single dose of foramsulfuron is not likely to cause acute health effects in the general population (including infants and children).

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Field corn residue trials conducted throughout Canada and the United States using foramsulfuron were acceptable. The MRL for field corn grain can be found in Proposed Registration Decision document PRD2008-05, *Foramsulfuron Technical Herbicide*.

Occupational Risks From Handling Option 35 DF Herbicide and Option 2.25 OD Liquid Herbicide

Occupational risks are not of concern when foramsulfuron is used according to label directions, which include protective measures.

Farmers and pesticide applicators mixing, loading or applying Option 35 DF Herbicide or Option 2.25 OD Liquid Herbicide, as well as field workers re-entering freshly treated fields, can come in direct contact with foramsulfuron on the skin or through inhalation of spray mists. Therefore, the label specifies that anyone mixing, loading, applying or involved in clean-up or repair activities with Option 35 DF Herbicide and Option 2.25 OD Liquid Herbicide must wear a long-sleeved shirt, long pants, socks and footwear and that anyone mixing, loading or involved in clean-up or repair activities must also wear chemical-resistant gloves. Considering these label requirements and that occupational exposure is expected to be brief because this herbicide is applied only once per year, risk to farmers, applicators or workers is not a concern.

Bystander exposure is expected to be much less than that of field workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Foramsulfuron Technical Herbicide Is Introduced Into the Environment?

Foramsulfuron is toxic to terrestrial plants. While foramsulfuron is not toxic to fish and aquatic organisms, the end-use products (Option 35 DF Herbicide and Option 2.25 OD Liquid Herbicide) have been found to be toxic to aquatic vascular plants. Therefore, buffer zones are required during application.

Foramsulfuron enters the environment when used as a herbicide on corn. Foramsulfuron is non-persistent in soil, slightly persistent in water and moderately persistent in sediment, while the major breakdown product is non-persistent in soil. Foramsulfuron is very mobile in soil and may leach to groundwater. The major breakdown product was found to be mobile in loamy sand but immobile in silt loam. Based on its low volatility, foramsulfuron residues are not expected in the air.

Foramsulfuron and its major breakdown product present a low risk to wild mammals, birds, earthworms, bees and other arthropods, aquatic invertebrates, fish, algae and aquatic plants. However, the end-use products were found to be a risk to terrestrial and aquatic plants. Therefore, a buffer zone of one metre is required for aquatic habitats for both Option 35 DF Herbicide and Option 2.25 OD Liquid Herbicide. For terrestrial environments, a buffer zone of 10 metres is required for Option 35 DF Herbicide and three metres for Option 2.25 OD Liquid Herbicide.

Foramsulfuron and its end-use products had been granted conditional registration with additional information required regarding the log K_{ow} for the transformation products of foramsulfuron, the log K_{ow} for the transformation products of the safener, and the toxicity of the end-use products Option 35 DF Herbicide and Option 2.25 OD Liquid Herbicide to aquatic vascular plants. The additional information was provided. However, the toxicity of Option 2.25 OD Liquid Herbicide to aquatic vascular plants is still unknown. Therefore, full registration cannot be granted for this end-use product at this time.

Value Considerations

What Is the Value of Option 35 DF Herbicide and Option 2.25 OD Liquid Herbicide?

Option 35 DF Herbicide and Option 2.25 OD Liquid Herbicide, postemergence herbicides, control both grasses and broadleaf weeds in field corn.

A single application of Option 35 DF Herbicide and Option 2.25 OD Liquid Herbicide provides effective control of a range of broadleaf and grassy weeds in field corn. It is also compatible with integrated weed management practices and conventional crop production systems. Since both end-use products are applied after weeds have emerged, farmers can better assess whether the herbicide is necessary or suitable for particular weed species.

Option 35 DF Herbicide and Option 2.25 OD Liquid Herbicide had been granted conditional registration with one of the conditions being that the lowest effective rate for lambsquarters, yellow foxtail, large crabgrass, barnyard grass and bristly foxtail be established. The registrant provided additional data to support the rate of 35 g a.i./ha for each of these weed species. The condition of registration has now been adequately addressed from a value perspective and no further data are required.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Option 35 DF Herbicide and Option 2.25 OD Liquid Herbicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Since there is a concern with users coming into direct contact with foramsulfuron on the skin or through inhalation of spray mists, anyone mixing, loading, applying or involved in clean-up or repair activities with Option 35 DF Herbicide and Option 2.25 OD Liquid Herbicide must wear a

long-sleeved shirt, long pants, socks and footwear, and anyone mixing, loading or involved in clean-up or repair activities must also wear chemical-resistant gloves.

Environment

A buffer zone of one metre is required for aquatic habitats for both Option 35 DF Herbicide and Option 2.25 OD Liquid Herbicide. For terrestrial environments, a buffer zone of 10 metres is required for Option 35 DF Herbicide and three metres for Option 2.25 OD Liquid Herbicide.

Other Information

The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Request a Reconsideration of Decision, www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

[5]As per subsection 35(1) of the *Pest Control Products Act.*

Appendix I Comments and Responses

Comments on Toxicity to Vascular Plants (*Lemna gibba*)–Option 35 DF Herbicide

Bayer CropScience indicated that in Appendix 1, Table 8 of the Proposed Registration Decision document PRD2008-05, *Foramsulfuron Technical Herbicide,* the Option 35 DF Herbicide no observed effect concentration (NOEC) for *Lemna gibba* is reported as 0.00018 mg of end-use product (EP) per litre. However, the supporting document Bayer CropScience submitted with this application reported the NOEC for *Lemna gibba* as 0.00028 mg a.i./L, or 0.0008 mg EP/L. Bayer CropScience therefore requested that the table be amended to correct this error, that is, that the stated NOEC value be changed from 0.00018 mg EP/L to 0.0008 mg EP/L.

Response

In the submitted *Lemna* sp. study, concentrations were reported in µg a.i./L rather than in µg EP/L, which is more representative in a study conducted with the end-use product. Therefore, values calculated by the environmental assessment division were converted to µg EP/L. However, there was a transcription error with regards to the calculated NOEC. In the original Data Evaluation Report and the consultation document, the NOEC was reported as 0.18 µg EP/L.

The error reported by the applicant with regards to the reported NOEC for Option 35 (foramsulfuron) to *Lemna* sp. was corrected from 0.18 µg EP/L to 0.8 µg EP/L. The NOEC was not used to determine any risk; therefore, this transcription error had minimal impact on the overall environmental assessment.

References

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

1.0 The Active Ingredient, Its Properties and Uses

PMRA 1180569 Material Accountability of Foramsulfuron (AE F130360), Analytical Profile of Production Batches, Bayer CropScience GmbH, Study No. PA04/013, May 19, 2004, 43 pages, DACO 2.13.3.

PMRA 1060303 Foramsulfuron: Analytical Method for the Determination of Foramsulfuron and its Metabolite Foramsulfuron Sulfonamide in Sediment by LC/MS/MS, Bayer CropScience, Analytical Method: FS-002-S05-01, July 29, 2005, 36 pages, DACO 8.2.2.2.

PMRA 1060304 Method of Analysis for the Determination of Residues of Foramsulfuron and its Metabolite AE F130619 in Surface and Drinking Water Using LC/MS/MS, Bayer CropScience, Method number: FS-003-W05-01, July 29, 2005, 23 pages, DACO 8.2.2.3.

PMRA 1060305 Analytical Method for the Determination of Foramsulfuron Sulfonamide (AE F153745) Residues in Biota, Method Number FS-001-A05-01, July 28, 2005, 42 pages, DACO 8.2.2.4.

2.0 Methods of Analysis

No new data were submitted.

3.0 Impact on Human and Animal Health

PMRA 961890 Stability of AE F130360 and AE F153745 Residues in Corn (forage, stover and grain) During Frozen Storage, USA, 1998 (Minimum Storage Interval of 616 Days). 06-February-2001. Lab Project Number: CF98R004A. AGREDOC Number:B003134. Study No. CF98R004. DACO 7.3

PMRA 1021724 Stability of AE F130360 and AE F153745 Residues in Corn (forage, stover and grain) During Frozen Storage, USA, 1998 (Minimum Storage Interval of 209 Days). 23-February -2000. Study Identification Number CF-98R-004. Aventis CropScience. DACO 7.3.

PMRA 1021725 Metabolism of [U-^{14}C-phenyl]-AE F130360 and [2-^{14}C-pyrimidyl]-AE F130360 in Corn Grown Under Field Conditions. 8-February-2000. Aventis CropScience, Environmental Chemistry Department, Pikeville, USA. Report No.: CF96E512. DACO 6.3.

PMRA 1021726 Poultry - Metabolism, distribution and nature of the residues in eggs and edible tissues of the laying hen. 12-October-1999. Lab Project ID: TO 96080. AgrEvo UK Limited. DACO 6.2.

PMRA 1021727 Cow - Metabolism, distribution and nature of the residues in milk and edible tissues. 28-October-1999. Lab Project ID: TOX 96079. AgrEvo UK Limited. DACO 6.2.

PMRA 1021738 At Harvest AE F130360 and Isoxadifen-ethyl Derived Residues in Field Corn Following Applications of AE F130360 and/or Isoxadifen-ethyl WDG at the Maximum Proposed Rates and the Shortest Proposed PHI, USA and Canada, 1997. 9-March-2000. Study No. CF-97R-01. Aventis CropScience. DACO 7.4.1.

PMRA 1021739 At Harvest AE F130360 and Isoxadifen-ethyl Derived Residues in Field Corn Following Applications of AE F130360 and/or Isoxadifen-ethyl WDG at the Maximum Proposed Rates and the Shortest Proposed PHI, USA and Canada, 1998. 15-March-2000. Study No. CF-98R-001. Aventis CropScience. DACO 7.4.1.

PMRA 1021740 AE F130360 and Isoxadifen-ethyl Derived Residues in Field Corn and Processed Corn Commodities Following Applications of AE F130360 and AE F122006 WDG at an Exaggerated Rate and the Shortest Proposed PHI, USA 1998. 28-February-2000. Study No. CF98R002. Aventis CropScience. DACO 7.4.5.

PMRA 1021741 Uptake of Residues of [U-phenyl-^{14}C]-AE F130360 and [2-pyrimidyl-^{14}C]-AE F130360 in Soil by Rotational Crops Under Confined Conditions. 10-June-1999. Laboratory Project ID 516CF. AgrEvo USA Company. DACO 7.4.3.

PMRA 1021742 At Harvest AE F130360 and AE F122006 Derived Residues in Rotational Crops Planted after Treatment of a Bare Plot with AE F130360 WDG and AE F122006 WDG at Selected Applications Rates and Rotational Intervals, USA, 1997. 22-February-2000. Study Identification Number CF-97R-02. Aventis CropScience. DACO 7.4.4.

PMRA 1021826 Multiresidue Method Testing for AE F130360 and AE F153745 According to PAM I, Appendix II, as Updated January, 1994. 11-January-2000. Lab Project ID #CF99R002. Laboratory Report Number 45656. DACO 7.2.4.

PMRA 1021827 Independent Laboratory Validation Of the Analytical Method for the Determination of Residues of AE F130360 and its Metabolite AE F153745 in Corn by Liquid Chromatography Using Mass Spectrometric Detection. 27-March-2000. Aventis Study Number CF00R001. Aventis CropScience. DACO 7.2.3.

PMRA 1054389 An Analytical Method for the Determination of Residues of AE F130360 and its Metabolite AE F153745 in Corn by Liquid Chromatography Using Mass Spectrometric Detection (MSD). 23-September-1999. Report No. CF/03/98. Aventis CropScience USA LP. DACO 7.2.1.

4.0 Impact on the Environment

PMRA 955915 2000, Stability of AE F130360 and AE F092944Residues in Soil During Frozen Storage, USA, 1998 (Storage Interval of 477 Days), B002761, DACO 8.3.2.

PMRA 955916 2000, Stability of AE F130360 and AE F122006 Derived Residues Following Fortification of Soil from a Field Dissipation Site with AE F130360 and AE F122006, Canada, 1997, B002775, DACO 8.3.2.

PMRA 955917 2000, Partion Coefficient - AE F130619 96.7% w/w., 99030514, DACO 8.2.1.

PMRA 955918 Partition Coefficient - AE F092944 98.5% w/w., 99030502, DACO 8.2.1.

PMRA 955919 2004, AE 0338795 Partition Coefficient 1- Octanol/Water (Shake Flask Method), PA04/048, DACO 8.2.1.

PMRA 955920 2000, Partion Coefficient - AE F153745 97.8% w/w., 99020508, DACO 8.2.1.

PMRA 961891 2004, Toxicity of AE F130360 01 WG70 to Duckweed (*Lemna gibba* G3) Under Static-Renewal Conditions, EBFSM002, DACO 9.8.6.

PMRA 961995 2004, Environmental Research Position Paper: Foramsulfuron + Isoxadifen Ethyl: Response to Canadian PMRA Deficiencies Identified in the Area of Water and Sediment Residue Chemistry, B004880, DACO 8.2.2.2.

PMRA 961998 2005, Rationale for an Exemption from the Requirement for Submission of a Seedling Emergence Study with Option 2.25SC Herbicide (formerly Tribute 2.25SC Herbicide), DACO 9.8.6.

PMRA 961999 2002, Aventis CropScience, Foramsulfuron Oil Flowable 22.5 g/L Formulation (AE F130360 01 1K05 A304) Toxicity to Duckweed, *Lemna gibba*., EBFSM002, DACO 9.8.6.

5.0 Value

PMRA 961894 2001, Efficacy: Small Scale Trials (Field), CANBYR001, DACO 10.2.3.3.

PMRA 962002 Efficacy: Small Scale Field Trials, DACO 10.2.3.3.